

National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Avenue S.W.
Suite 729-D
Washington, D.C. 20201

Submitted electronically at: <https://www.healthit.gov/isa>

Re: 2018 Interoperability Standards Advisory Reference Edition

Dear Mr. Posnack,

Thank you for this opportunity to comment on the 2018 Interoperability Standards Advisory Reference Edition.

As an electronic health records (EHR) developer based in Verona, Wisconsin, Epic actively encourages interoperability. Our first sites went live with Epic's interoperability application, Care Everywhere[®], in 2008. As of 2014, all U.S.-based Epic organizations—which includes over 1,800 hospitals and 34,000 clinics—use Care Everywhere to exchange patient data with each other and with healthcare institutions that use other EHR systems. Over 2 million patient records are exchanged daily using Care Everywhere.

Epic participates in industry standards development in order to further interoperability efforts, including Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), National Council for Prescription Drug Programs (NCPDP), Standards & Interoperability Framework, and others. Epic staff currently co-chair several HL7 and IHE committees. In addition to developing and implementing standards, we've taken a leadership role in the industry in interoperability governance. We helped to co-found The Sequoia Project's Carequality (www.carequality.org) initiative, which aims to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, and public HIEs, to interoperate freely with one another.

Given our strong support of interoperability, we urge consideration of the following as ONC continues to develop the ISA.

Sincerely,



Peter DeVault, Vice President
Epic

General Comments

We appreciate the incorporation of feedback from previous years and the opportunity to continue to contribute to the selection of interoperability standards. We agree that most of the standards proposed are appropriate for facilitating interoperability, and we've commented only in places where we disagree or have additional input.

We note that the standards identified are at various stages of implementation and adoption. Users of the Standards Advisory will need to account for appropriate implementation timelines for their particular purpose.

We appreciate the increase of specificity by including the specific Fast Healthcare Interoperability Resources (FHIR) profile in sections that reference it. However, there are still several sections missing this detail (e.g., III-H: Query - Data Element Based Query for Clinical Health Information). We recommend that ONC continue to add specific FHIR profiles for each need to eliminate the inevitable variation that will occur in the absence of specificity and provide a clear path for implementation. This would support the overall direction of the Standards Advisory to address specific interoperability needs by including specific implementation guides and standards.

Purpose

The ISA's stated purpose of providing the industry with a "single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs" seems reasonable, though we observe that the purpose seems focused on U.S. industry specifically. ONC should clarify their intent since there are other considerations for international use cases and standards adoption.

Comments on Informative Characteristics

#2: Implementation Maturity

We do not believe we could use the definitions given to establish whether standards are being piloted or in production use. These categories are separate and not mutually exclusive concepts because a standard could be both in production and in a pilot stage. If the intent is for these categories to be mutually exclusive, ONC should include a threshold for when a standard exceeds use on a "limited scale" and can be considered to be used in "Production." ONC should also clarify how this would differ from the Adoption Level characteristic.

#3: Adoption Level

The adoption level metric would be more reliable and consistent if it was informed by quantitative data about the rate of implementation. It's not possible to know whether adoption levels are accurate when there isn't a benchmark to compare it to.

Comments on Proposed Standards

I-C: Family Health History

Interoperability Need: Representing Patient Family Health History

It is true that “some details around family genomic health history may not be captured by SNOMED CT.” SNOMED does not capture many rare genetic disorders or molecular tumor biomarkers. Initiatives like Monarch and Online Mendelian Inheritance in Man (OMIM) are working to improve capturing family genomic health history and facilitate sharing this data for research. ONC should include the work these groups are doing as considerations in the ISA.

I-E: Health Care Providers

Proposed Interoperability Need: Representing Health Care Locations

While NPI is used for provider identification and TIN is used for organization-level identification, they cannot be reliably used for unique identification of a physical location. CCN is meant for entities that receive reimbursement from CMS, so it will not work for social services and non-medical community resources. It is also sometimes applied to a whole organization instead of an individual location. Having a unique location identifier is important when denoting that two sets of location data are representing the same place.

Consider a scenario where a healthcare organization is compiling information about local skilled nursing facilities. This organization received address and quality data from CMS and phone and fax numbers from a state HIE. By simply reviewing the data received from CMS and the HIE, this healthcare organization is unable to match the address and quality information with the phone and fax number information. With a national identifier, the health system would be able to match this data with a skilled nursing facility’s location and be able to create a comprehensive record of this location for clinicians to use.

Currently there isn’t a standard that meets this interoperability need. We encourage ONC to add this interoperability need to the ISA and track these considerations there.

I-R: Sex at Birth, Sexual Orientation and Gender Identity

Interoperability Need: Representing Patient Sex (At Birth)

Increasingly, the Sex Assigned at Birth is left unassigned as traits resolve themselves for infants of ambiguous genitalia. The HL7 V3 NullFlavor code UNK does not properly represent this classification, as “unknown” could also mean that the value is unknown to the person at the time of documentation (e.g., for a new adult patient who registers with an organization). We recommend adding a value for “Left Unassigned” to indicate cases where clinicians do not assign a sex at birth.

I-S: Social, Psychological, and Behavioral Data

Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)

While the identified HARK (Humiliation, Afraid, Rape, Kick) screening could be a viable option to identify women who have experienced intimate partner violence, this screening has yet to be clinically validated on men, nor is there a mention of how this applies to individuals in the LGBT community. We encourage ONC to track these considerations in the ISA.

Proposed: I-X: Health Status

Proposed Interoperability Need: Representing Patient Health Status

There is an interoperability need to express the health status of a patient.

ONC 2015 Edition Certification includes the HL7 HealthStatus Value Set (urn:oid:2.16.840.1.113883.1.11.20.12) as a way to document health concerns section within the (b)(9) Care Plans document. This value set could be used to meet this interoperability need, however it has the following gaps:

The set should include these three codes only: General health good, General health poor, Chronically ill. The other codes in the value set are duplicative of these codes (e.g. Alive and Well, Symptom free, and Severely ill) or do not represent a health status (Deceased, Disabled, Severely disables, or In remission).

We recommend that ONC add this category and interoperability need as well as track these considerations within the ISA.

II-I: Electronic Prescribing

Interoperability Need: Cancellation of a Prescription

ONC requested feedback on the adoption level of NCPDP SCRIPT (v10.6) for the Cancel transaction. Based on our experience, adoption of NCPDP SCRIPT (v10.6) for the Cancel transaction has increased over the past year and would be better represented as low-medium (two circles).

Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription

ONC requested feedback on the adoption level of NCPDP SCRIPT (v10.6) for the RxChange transaction. As RxChange is a new requirement as part of the 2015 ONC Certification and major pharmacy networks are still rolling out their support, we believe today's adoption of the RxChange transaction in production environments is low (one circle). We anticipate an increase in adoption over the next two years.

An additional bullet point that states “Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange” is listed in the Limitations, Dependencies, and Preconditions for Considerations sections of the Cancellation of a Prescription, A Prescriber’s Ability to Grant a Refill Request to the Pharmacy, and the A Prescriber’s Ability to Create a New Prescription to Electronically Send to a Pharmacy interoperability needs. This bullet point also applies to the Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription interoperability need. Therefore, we recommend ONC add it.

Interoperability Need: A Prescriber’s Ability to Create a New Prescription to Electronically Send to a Pharmacy

ONC requested feedback on the adoption level of NCPDP SCRIPT (v10.6) for the NewRx transaction. The NewRx transaction is a well-used and understood standard in the industry. It has been used for several years and allows a pharmacist to start working on a patient’s prescription quicker. We believe today’s adoption of the NewRx transaction in production environments is high (five circles).

Interoperability Need: A Prescriber’s Ability to Obtain a Patient’s Medication History from a Prescription Drug Monitoring Program

The second bullet point in the Limitations, Dependencies, and Preconditions for Considerations section (“Both the prescriber and the receiving pharmacy or pharmacy benefits manager (PBM) must have their systems configured for the transaction in order to facilitate successful exchange.”) should be removed because this doesn’t apply to this interoperability need. The EHR would send a medication history request to a state-run Prescription Drug Monitoring Program (PDMP) and the PDMP returns the dispense information to the EHR. The pharmacy is not involved.

ONC requested feedback on the adoption level of NCPDP SCRIPT (v10.6) for the RxHistory transaction for this interoperability need. The ability to electronically request a patient’s medication history from a PDMP is new and its implementation depends on the state’s readiness. As many states rely on a Single Sign On (SSO) solution rather than the RxHistory transaction, we believe today’s adoption in production environments is low to medium (two circles).

Interoperability Need: Prior Authorization Cancel Request

The implementation specification should be updated from NCPDP SCRIPT Version 10.6 to NCPDP SCRIPT Version 2013101.

II-Q: Patient Preference/Consent

Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers

When evaluating standards for patient preference to access and/or share health information with other providers, there are two major considerations: Chart Segmentation and Consent. We discuss each below.

Chart Segmentation

There is not currently an acceptable chart segmentation standard. If Advanced Patient Privacy and Consents (APPC) or a different standard is advanced, it needs to be accompanied by guidance addressing the safety concerns inherent in such standards. For example, providers would want indicators when records have been segmented or potentially segmented so they do not erroneously trust that they have a comprehensive medical history.

We recommend that patients who are interested in segmenting their health information opt out of clinician-to-clinician exchange and instead use the features available in personal health records (PHRs) to construct a document with information they feel comfortable sharing.

We further recommend that guidance be withheld on the topic of chart segmentation until significant progress and consensus is accomplished with regard to its inherent difficulties.

Consent

Another consideration is establishing a consent process across organizations to allow for trusted and quick health information exchange. In the Basic Patient Privacy Consent (BPPC) and APPC standards, the affinity domain defines the consent, meaning that different healthcare groups connecting to the repository can have different rules around when patients need to give consent and what they can give consent for. The United States does not have well-defined affinity domains, which is necessary precursor before BPPC can be considered a practical solution.

A clear affinity domain structure also defines delegated consent, a concept where one healthcare organization is able to capture consent on behalf of another healthcare organization. Trusting that the organization asking for the patient's record has received the patient's consent without needing to review the form allows the treating organization to pull the patient's record sooner and the patient receives safe care quicker.

We recommend that ONC include the Carequality Patient Consent Framework in the ISA. Carequality is working on an initiative to create consensus-based agreements surrounding consent forms, expanding Care Everywhere's Rules of the Road to include multiple vendor platforms and networks. This will resolve many of the concerns around care delays as organizations who have agreed to these consent guidelines will be able to trust that other organizations also on the agreement are collecting consent in a manner consistent with their policies.

II-R: Public Health Reporting

The “Federally Required” column is inconsistently documented for the interoperability needs under this section. ONC correctly marked the standards for the following four interoperability needs as federally required.

- Reporting Administered Immunizations to Immunization Registry
- Reporting Syndromic Surveillance to Public Health Agencies
- Reporting Cancer Cases to Public Health Agencies
- Electronic Transmission of Reportable Lab Results to Public Health Agencies

The standards for these three interoperability needs are new for Meaningful Use Stage 3 and should be marked as federally required:

- Case Reporting to Public Health Agencies
- Sending Health Care Survey Information to Public Health Agencies
- Reporting Antimicrobial Use and Resistance Information to Public Health Agencies

Interoperability Need: Reporting Birth Defects to Public Health Agencies

We recommend expanding the scope of this interoperability need to include birth reporting to Public Health Agencies. Birth reporting is a function performed by every vital records jurisdiction with input from EHR records and is important for national planning. However, the processes by which birth information is reported from an EHR to a public health registry is neither standardized nor consistent. This is an important area for vital records and an important place to establish consistency. This expanded interoperability need should include the [HL7v2](#) and [IHE Birth and Fetal Death Reporting \(BFDR\)](#) profiles.

Proposed Interoperability Need: Reporting Death Records to Public Health Agencies

ONC should add an additional interoperability need to section II-R as there is a distinctly separate use case for vital records death reporting. Death tracking can be used to prevent identity theft and can be used by governments to track outbreaks of fatal diseases. Death reporting is a function performed by every vital records jurisdiction with input from EHR record, but the processes by which death information is reported from an EHR to a public health registry is neither standardized nor consistent. We encourage ONC to include more standards and implementation specifications as they relate to death reporting to public health agencies.

Interoperability Need: Reporting Death Records to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-VRDR (Vital Records Death Reporting)	Balloted Draft	Production	●○○○○	No	Free	N/A

II-T: Segmentation of Sensitive Information

It is premature to propose a data segmentation standard, whether DS4P or a different standard, without addressing the safety concerns inherent in such standards as a limitation. The [Data Segmentation for Privacy Initiative Version 1.1](#) states: “Patient safety implications of sending partial datasets, with portions of data removed to comply with Patient Consent Directives or jurisdictional regulations is a policy consideration and not within the scope of this Use Case” (page 9). Patient safety is a crucial aspect of data segmentation standards due to the impact of removing clinically relevant information from patient charts so that it is not accessible to providers.

Chart Segmentation

There is not currently an acceptable chart segmentation standard. If an existing chart segmentation standard is advanced, it needs to be accompanied by guidance addressing the safety concerns inherent in such standards. For example, providers would want indicators when records have been segmented or potentially segmented so they do not erroneously trust that they have a comprehensive medical history.

We recommend that patients who are interested in segmenting their health information opt out of clinician-to-clinician exchange and instead use the features available in personal health records (PHRs) to construct a document with information they feel comfortable sharing.

We further recommend that guidance be withheld on the topic of chart segmentation until significant progress and consensus is accomplished with regard to its inherent difficulties.

III-D: Healthcare Directory, Provider Directory

Interoperability Need: Listing of Providers for Access by Potential Exchange Partners

Currently, over 90 percent of the healthcare organizations we support are exchanging provider directories that contain demographic information and Direct addresses for providers, hospitals, clinics, and other healthcare facilities. Healthcare organizations use these directories to successfully exchange summary of care documents during transitions of care.

Based on our experience, we agree that a standard way of sharing provider data will improve care coordination by facilitating the discovery of the next healthcare provider during a transition of care. IHE’s Healthcare Provider Directory (HPD), however, is not mature enough to support provider

directories for healthcare organizations. HPD is currently in trial status and doesn't appear to be ready to move to the final test status.

HPD also has a number of flaws that will make it very challenging to implement and use practically. For example, HPD doesn't support associations between key data elements. If a provider has three addresses and three fax numbers in a directory, a directory consumer can't tell which address goes with which fax number. If a directory consumer chooses the wrong fax number, patient health information may be transmitted to the wrong place, which is a potential HIPAA breach and privacy issue.

There is no widely adopted alternative to HPD, but the draft standard for FHIR already presents a better alternative. Like HPD, FHIR is also in draft and is not widely adopted. However, it has already solved key problems we've identified with HPD. Within FHIR's administrative module, a provider can be associated with a physical address, phone number, fax number, and the specialty he or she practices at this address.

We recommend ONC includes these considerations in the "Limitations..." section of the ISA. We also encourage ONC to reference the work being done by the Healthcare Directory – Interoperability Tiger Team to design a national provider directory using FHIR.

III-J: Consumer Access/Exchange of Health Information

We encourage ONC to be more specific on which security patterns for consideration apply to which standard within these interoperability needs. When using the SMART on FHIR model, we expect the authentication model to be OAuth2. Except for "Secure Communication", the security patterns listed under these interoperability needs do not apply. For example, when using OAuth2 for authentication, the client requesting permission is given a token. When the client then sends information to the EHR, the token, not the user details or user role, is passed for authentication. Consequently, the security patterns "User Details" and "User Roles" are not applicable in cases when FHIR is used.

Interoperability Need: Push Patient-Generated Health Data into Integrated EHR

For push use cases, Direct has gained traction for provider-to-provider communication. However, it is a complicated standard to use when patients are pushing their data into an EHR. FHIR, being a RESTful solution, is more appropriate for this use case. For example, a patient purchases a glucometer and wants to send their glucose readings to their patient portal. If this integration is done via Direct, each reading from the glucometer would be sent in a large XML message that has superfluous information for this use case, e.g., demographic information. If this integration is done via FHIR, the transaction would be more specific to the information that needs to be sent for this use case, simplifying the integration. In general, we do not think Direct should be considered a viable option for new use cases.

We believe the “Patient Consent Information” bullet does not apply to this interoperability need. The user for this interoperability need is the patient. By using SMART on FHIR, the patient explicitly consents to their data being shared. Thus, patient consent information is not sent as part of the transaction.

Interoperability Need: Remote Patient Authorization and Submission of EHR Data for Research

We believe the “Patient Consent Information” bullet does not apply to this interoperability need. The user for this interoperability need is the patient. By using SMART on FHIR, the patient explicitly consents to their data being shared. Thus, patient consent information is not sent as part of the transaction.

Questions

General

17-1 – In what ways has the ISA been useful for you/your organization as a resource? ONC seeks to better understand how the ISA is being used, by whom, and the type of support it may be providing for implementers and policy-makers.

We are deeply involved in standards organizations and industry discussions about interoperability. We primarily see our role as a contributor to the ISA, adding to it from our experience in the industry because we hope that when stakeholders are starting a new interoperability initiative (e.g. a state setting up a registry), they are looking to the ISA for standards they could pull from.

17-2 – Over the course of 2017, various new functionality has been added to the ISA to make it a more interactive and useful resource (e.g., print-friendly pages, change notifications, advanced search functionality, etc.). Are there additional features or functionalities that would enhance the overall experience?

Currently, if a stakeholder wanted to access the full ISA in one view, they have two options:

- Accessing the 2017 ISA Reference Edition
- Clicking “View ISA as a Single Page”

The 2017 ISA Reference Edition is not the most up-to-date version and the “View ISA as a Single Page” removes the ISA use case headers and interoperability needs do not appear in the same order they appear in other forms of the ISA. This makes it difficult to do a general review of the ISA. We recommend improving the “View ISA as a Single Page” web page to keep the same Use Case headers and order as in the pdf version of the ISA.

Section I: Vocabulary/Code Set/Terminology Standards

17-4 – Are there additional Interoperability Needs (with corresponding standards) that represent specific [sociodemographic, psychological, behavioral or environmental domains](#) that should be included in the ISA?

We recommend using the Generalized Anxiety Disorder 7 (GAD-7) assessment to gauge anxiety. This is represented using the LOINC code 69737-5.

Section II: Content / Structure Standard and Implementation Specifications

17-5 – A new interoperability need, [Reporting Birth Defects to Public Health Agencies](#) was added to Section II-R: Public Health Reporting. Please review and provide comment about the accuracy of the attributes.

We recommend expanding the scope of this interoperability need to include birth reporting to Public Health Agencies. Birth reporting is a function performed by every vital records jurisdiction with input from EHR records and is important for national planning. However, the processes by which birth information is reported from an EHR to a public health registry is neither standardized nor consistent. This is an important area for vital records and an important place to establish consistency. This expanded interoperability need should include the [HL7v2](#) and [IHE Birth and Fetal Death Reporting \(BFDR\)](#) profiles.

Section V: Administrative Standards and Implementation Specifications

17-11 – For Interoperability Need: [Health Care Claims or Equivalent Encounter Information for Dental Claims](#), feedback is requested from the dental community on enhancements to the transaction to increase uptake on electronic transactions.

There are two teeth numbering systems used by dentists in the United States – the ADA (American Dental Association) system and the ISO (International Standards Organization Designation) system. The ISO system is recommended by the World Health Organization and is used internationally.

Currently, dentists using the paper dental claims form (ADA 2012) are able to choose the tooth numbering system they prefer. However, the only existing electronic standard (X12) supports the ADA system, not the ISO system. Therefore, dentists switching to the electronic form using this standard lose flexibility. Dentists that want to use the ISO system either need to switch to the ADA system for electronic documentation or continue to use the paper form. As a result, if the X12 standard continues to not support the ISO system, or another standard isn't created that supports the ISO system, we expect adoption by dentists to be low. We encourage ONC to include these considerations in the ISA.

17-12 – For Interoperability Need: [Enrollment and Disenrollment in a Health Plan](#), feedback is requested on the use of the adopted enrollment transaction, its value to the industry, and any enhancements that could be made to increase utilization.

ONC requested feedback on the adoption level of the ASC X12 (834) standard. As the Healthcare Marketplace was the first national implementation of 834, health plans and client systems are still rolling out their support. We believe today's adoption of the 834 standard in production environments is low (one circle). We anticipate a significant increase in adoption over the next few years.

The 834 standard has brought value to the claims industry as it removes the startup cost of building new interfaces for every connection to another system and decreases the maintenance overhead.

17-14 – For Interoperability Need: [Health Care Payment and Remittance Advice](#), feedback is requested on how the transaction or use by the submitter and/or receiver can be improved to enhance its use and increase the value of the transaction.

Today, health care payments can come from insurance companies or patients. Flex payments are a hybrid of the two – these are payments sent by the insurance company as part of 835 transactions and handled in the billing system as patient payments. Therefore, there are special considerations around flex payments. One way of resolving this is to send a “Payment Type” field to indicate whether a payment is a flex payment. Currently, flex payments are inconsistently implemented across standards and payers. Some payers send this information via [CAR codes](#) (CO 187) while others send information in a different manner. Having a standardized way of sending flex payments would make the processing of these payments easier.